3-23-07

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949-1002.

EXHIBIT 3
DATE 3-23-07
SB 521

Montana Pharmacists Association
Senate Bill 521 (Substitution of Antiepileptic Drugs)
Talking Points

Current System Addresses Safety Concerns of Generic Medications

- Montana statute allows physician to write "dispense as written" if in his/her medical opinion a brand-name medication is medically necessary. Pharmacists are prohibited from substituting a generic equivalent when "dispense as written" has been indicated by the prescriber.

- The FDA is the appropriate body to determine the bioequivalence of all drug products, including antiepileptic medications.

- The FDA has concluded that "there are no documented examples of a generic product manufactured to meet its approved specifications that could not be used interchangeably with the corresponding brand-name drug".

- For both brand-name and generic drugs, FDA works with pharmaceutical companies to assure that all drugs marketed in the U.S. meet specifications for identity, strength, quality, purity, and potency.

- The FDA requires rigorous tests and procedures to assure that the generic drug is interchangeable with the brand-name drug under all approved indications and condition of use.

- In addition to tests performed prior to market entry, the FDA regularly assesses the quality of products in the marketplace and thoroughly researches and evaluates reports of alleged drug product inequivalence. To date, there are no documented examples of a generic product manufactured to meet its approved specifications that could not be used interchangeably with the corresponding brand-name drug.

- Questions have been raised in the past, regarding brand name and generic products about which there could be concern that quality failures might represent a public safety hazard. The FDA has performed post-marketing testing on many of these drugs to assess their quality. In one instance, more than 400 samples of 24 marketed brand-name and generic drug products were tested and found to meet established standards or purity and quality. Because patients may pay closer attention to their symptoms when the substitution of one drug product for another occurs, an increase in symptoms may be reported at that time, and anecdotal reports of decreased efficacy or increased toxicity may result. Upon investigation by FDA, no problems attributed to substitution of one approved drug product for another has occurred.

Practical/Financial Concerns

- Antiepileptic medications are often used for indications other than epilepsy, SB-521 would require pharmacists to contact prescribers to determine reason for antiepileptic use. Many phone calls would need to be made to prescriber offices.

- Most 3rd party payers, including Montana Medicaid require that generic medications be preferentially used due to the lower cost compared to brand-name medications. SB-521would increase a patient's out of pocket expense for antiepileptic medications. It would also increase the amount of Medicaid dollars spent on antiepileptics with no evidence to support increased efficacy or safety. A fiscal analysis of the impact on state spending for antiepileptics should be considered.

- Drug product selection decisions should be made by patients in collaboration with their health care providers. (physician, pharmacist). SB-521 interferes with this and is unnecessary.

NPA
Nebraska Pharmacists Association

NEBRASKA PHARMACISTS ASSOCIATION
OPPOSITION TO LB 631
Joni Cover, Executive Vice President
February 15, 2007

LB 631 has been introduced by Senator Cap Dierks for the American Academy of Neurology to amend the *Drug Product Selection Act* to mandate that before a pharmacist substitutes and dispenses a drug to a patient for treatment of epilepsy (a prescription presented without the DAW, NDPS, or similar notations written on the prescription), that the pharmacist must get written permission from both the prescriber and patient before a switch can occur. This legislation is unnecessary because of existing law, burdensome to pharmacists, and costly to patients, taxpayers and insurance companies.

- Current law allows for NO substitution of medications by a pharmacist if the prescriber indicates on the prescription or verbally in the case of an oral prescription that no drug product selection is allowed, or no generic substitution, dispense as written or words or notations of similar import are specified. Nebraska's Drug Product Selection Act allows the substitution by a pharmacist of any bioequivalent drug unless expressly prohibited by a practitioner (71-5401 through 71-5409).

- LB 631 will create obstacles to existing generic substitution practices that are often mandated by insurance companies, pharmacy benefit managers and Nebraska Medicaid through existing third party contracts.

- Brand manufacturers should not be allowed to carve out entire therapeutic classes from generic substitution laws as this will lead to patients who suffer from epilepsy or whatever "carved out medical condition" having less access to affordable generic medication, which increases the cost of prescription drugs for consumers and tax payers.

- Because of the off-label prescribing practices of many physicians, how are pharmacists supposed to know that the drug being dispensed is for the treatment of epilepsy, unless the prescriber writes the diagnosis on the prescription. (see the handout of brand and generic medications prescribed and cost)

- Pharmacists are being accused of substitution medications in spite of the "notations" indicated on the prescription. If that is occurring, the NPA supports those pharmacists being reprimanded by the Nebraska Board of Pharmacy. However, the NPA checked with the Nebraska Board of Pharmacy and the state's pharmacy inspectors and investigators to find out how many complaints were filed and how many pharmacists were prosecuted for substituting medications without authorization from the physician when the physician had indicated that substituting was not allowed. According to the state inspector, only a couple of complaints had been filed in the last two years by patients who wanted brand name drugs (although the prescription did not indicate for the pharmacist that substitution was not allowed) and the pharmacist switched them to generic, and no one has been prosecuted. We assume the insurance company mandated the switch in each of these cases.

- LB 631 will be a financial burden on pharmacists unless they are allowed to charge patients the difference between the generic drug the insurance company will pay for and the brand they won't pay for. Many third party contracts do not allow the pharmacies to charge the patient the difference.

- The FDA approves generic substitution for generically equivalent drugs that save money for the patient, employers, Medicaid, and insurance carriers. In 1998, the FDA stated that "products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is a brand name or generic drug product."

- Physicians will be burdened by the number of callbacks from pharmacies, which will increase the amount of time it takes to fill the patient's prescription and may even jeopardize patient care.

- This legislation has unsuccessfully been introduced in 10 other states this year. It is unfortunate that the brand named drug manufacturers are using a disease like epilepsy and organ transplants to push their "narrow therapeutic indications" tactics across this country. And, shame on the pharmacists that work for the drug companies in supporting these tactics when they know that this isn't about patient care but about towing the company line!

We respectfully request that the Health & Human Services Committee vote to **Indefinitely Postpone** LB 631.